

REMARKS

Claims 1-25 are currently pending in this application. Claim 19 stands withdrawn. Claims 1, 2 and 17 are amended herein. Support for the claim amendments can be found throughout the application as originally filed, *inter alia*, on page 9, paragraph [024]. Accordingly, Applicants submit that no new matter is introduced into the application by way of the instant amendments. Claims 22, 24 and 25 are cancelled herein without prejudice or disclaimer as to the subject matter of the cancelled claims. Applicants respectfully reserve the right to prosecute the subject matter of the cancelled claims in one or more continuation or divisional applications. Upon entry and consideration of these amendments and remarks, claims 1-21 and 23 will remain pending.

In response to the Office Action, Applicants provide the following remarks:

Rejection Under 35 U.S.C. § 102

Claims 2 and 4 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Rubin (U.S. Patent No. 5,034,415). (*See* Office Action at page 4.) The Office Action asserts that Rubin teaches that EPA and DHA mixtures are useful for treating diabetes mellitus, and that compositions comprising DHA and EPA can replace butter and/or ordinary margarine or cooking oil.

Applicants respectfully disagree and traverse this rejection.

In order for a reference to anticipate under 35 U.S.C. § 102(b), the reference must disclose all elements of the claimed invention. The claimed invention is directed to methods for improving glucose control and treating diabetes comprising administering DHA to a patient/individual wherein the DHA is in the form of a triglyceride oil and is substantially free of EPA. Applicants submit that Rubin addresses the use of free fatty acids derived from marine animal oil, linseed oil, and soybean oil, and that, as such, the reference does not anticipate the claimed subject matter.

Applicants note that the Office Action also states that "... Rubin teaches treatment of patients suffering from diabetes mellitus with sardine oil containing DHA in triglyceride form, and with sardine oil after hydrolysis of the acids and removal of the glycerin. Applicants' claimed limitation of administering DHA in triglyceride oil has been conducted by Rubin's experiment on column 9 ..., wherein the treatment of adult diabetic were administered fish oil comprising triglyceride." *See* Office Action, page 3.

Applicants submit that the experiment reflected in column 9 of Rubin states that patients suffering from diabetes mellitus were treated with sardine oil (i.e., fish oil) containing DHA in the triglyceride form, and with sardine oil *after* hydrolysis of the acids and removal of the glycerine. As stated by Rubin in column 5, "... when extracted from fish oils these acids [DHA and EPA] are generally present in amounts of approximately 35% EPA/65% DHA, ..." *See* Rubin, column 5, lines 19-22. Thus, fish oils as taught by Rubin are disclosed generally as containing a substantial amount of EPA.

Furthermore, Applicants submit that Rubin actually promotes the inclusion of higher amounts of EPA. For example, Rubin states that "[p]referably the source fish are obtained from as cold an environment as possible ... fish from cold environments are higher in EPA than warmer water fish. Furthermore, even greater yields of EPA can be obtained if the fish are raised in a controlled environment. If the fish are fed a diet rich in linoleic acid and maintained in salt water at 9°C, optimum amounts of EPA will be produced." *See* Rubin, col. 6, lines 37-48. (emphasis added).

For the reasons set forth above, Applicants submit that Rubin does not teach each and every element of the invention as claimed, and therefore does not anticipate the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2 and 4 as allegedly anticipated by Rubin under 35 U.S.C. § 102(b).

Rejections Under 35 U.S.C. 103

A. Rubin in view of Remmereit et al.

Claims 1, 3, 5-9 and 20-25 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rubin in view of Remmereit *et al.* (U.S. Patent 6,440,931 B1). (See Office Action at page 5).

Applicants respectfully disagree and traverse this rejection.

Applicants submit that Rubin, considered alone or in combination with Remmereit, neither teaches nor suggests the claimed invention and does not render the claimed invention obvious. Even if, assuming purely for the sake of argument, the skilled artisan would have been motivated, as the Office Action asserts, to employ Rubin's composition to treat diabetes chronically because diabetes mellitus is a chronic disorder in view of Remmereit, this would not have resulted in the presently claimed invention, because Rubin does not teach or suggest the invention as presently claimed. Rubin's deficiencies are presented above under the rejection under 35 U.S.C. § 102, and are repeated and incorporated by reference herein as applied to the current rejection of claims 1, 3, 5-9 and 20-25. In effect, Rubin, by promoting inclusion of higher amounts of EPA, teaches away from the claimed invention. Remmereit does not remedy the deficiencies of Rubin. Therefore, the claimed invention is not rendered obvious by the cited references.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3, 5-9 and 20-25 under 35 U.S.C. 103(a).

B. Rubin in view of Remmereit et al. and Harris et al.

Claims 10-18 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rubin in view of Remmereit *et al.*, as applied to claims 1, 3, 5-9 and 20-25 above, and further in view of Harris *et al.*

Applicants respectfully disagree and traverse this rejection.

The deficiencies of Rubin and Remmereit have been addressed above in connection with the rejection of claims 1, 3, 5-9 and 20-25, and are repeated and incorporated by reference herein as applied to the current rejection of claims 10-18. The references, considered individually or in combination, fail to teach or suggest the claimed invention and thus do not render the claimed invention obvious. Applicants submit that the deficiencies of the primary reference are not remedied by Harris' general technical teachings regarding diagnostic classes, and further submit that the recited combination of references would not have lead to the invention as presently claimed.

For the reasons set forth above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 10-18 under 35 U.S.C. 103(a).

CONCLUSION

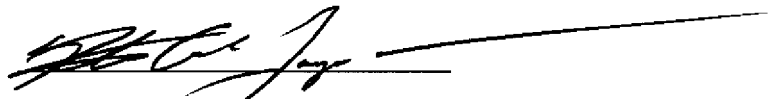
An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: May 14, 2009

By:



Robert C. Lampe III
Registration No. 51,914

Hunton & Williams LLP
1900 K Street, N.W., Suite 1200
Washington, D.C. 20006-1109
(202) 955-1500 (Telephone)
(202) 778-2201 (Facsimile)